Asia Pacific – New Regulations Update

Topics

- Overview of New and/or Revised Regulations in Asia Pacific
- Details of the Key Changes
- Key Challenges
- Summary

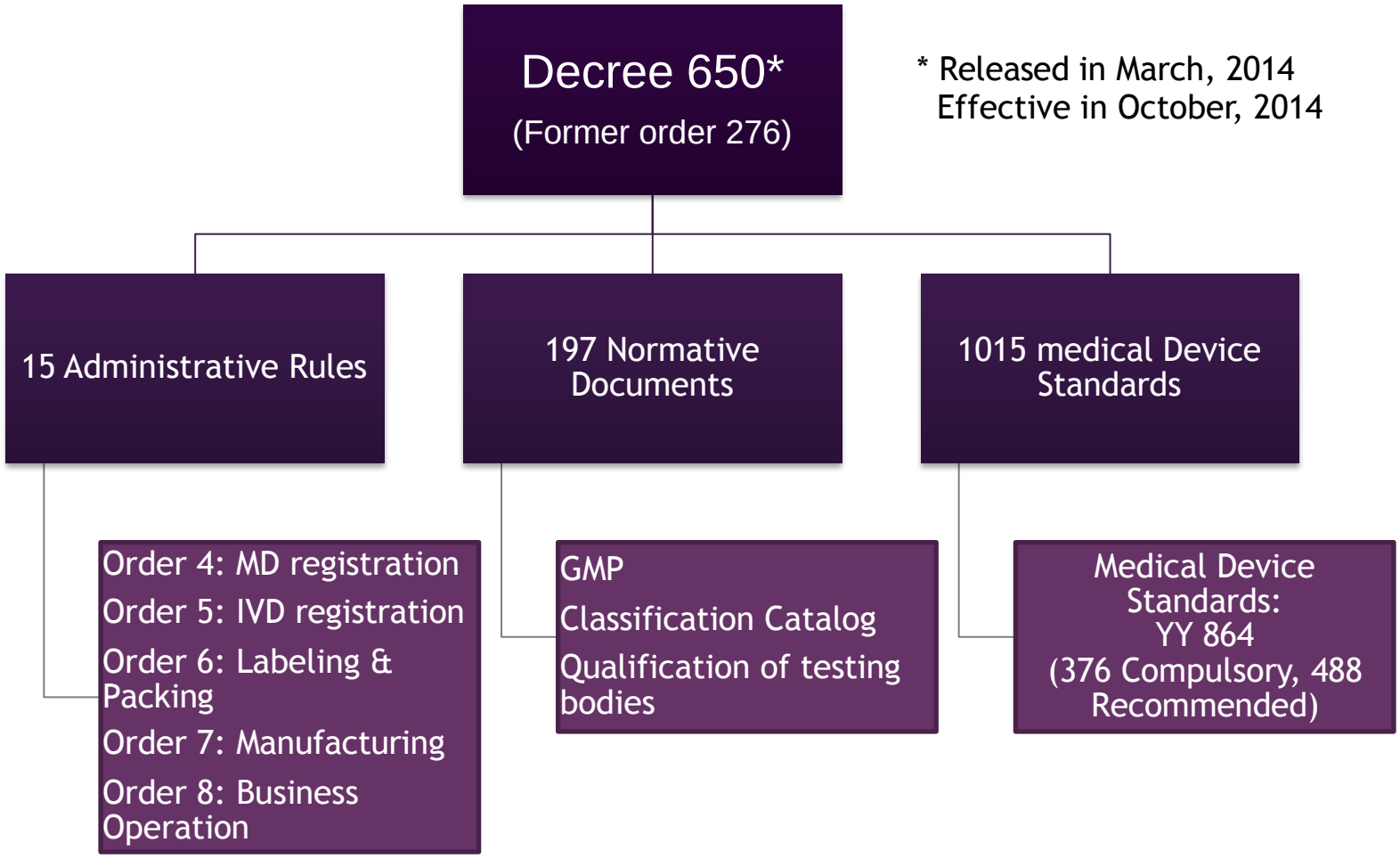
Overview of New and/or Revised Regulations in Asia Pacific

Country	Law/Regulations	Effective Date
China	Decree 650	Effective Oct 2014
India	MOH Notification (India Specific Labeling of Medical Device)	Effective Sep 2014
Japan	PMD Act	Effective Nov 2014
Malaysia	Act 737 (Enforcement of medical device registration)	Effective Jun 2015
Philippines	IVD Regulation	Effective Feb 2015
South Korea	Medical Device Act	Effective Nov 2014

New Regulation Update – China

- China Decree 650 framework
- Key changes in registration requirements
- Clinical trial impact on product registration timeline in China

Framework of Decree 650



Key Changes in Registration Requirements

Making complexity in registration

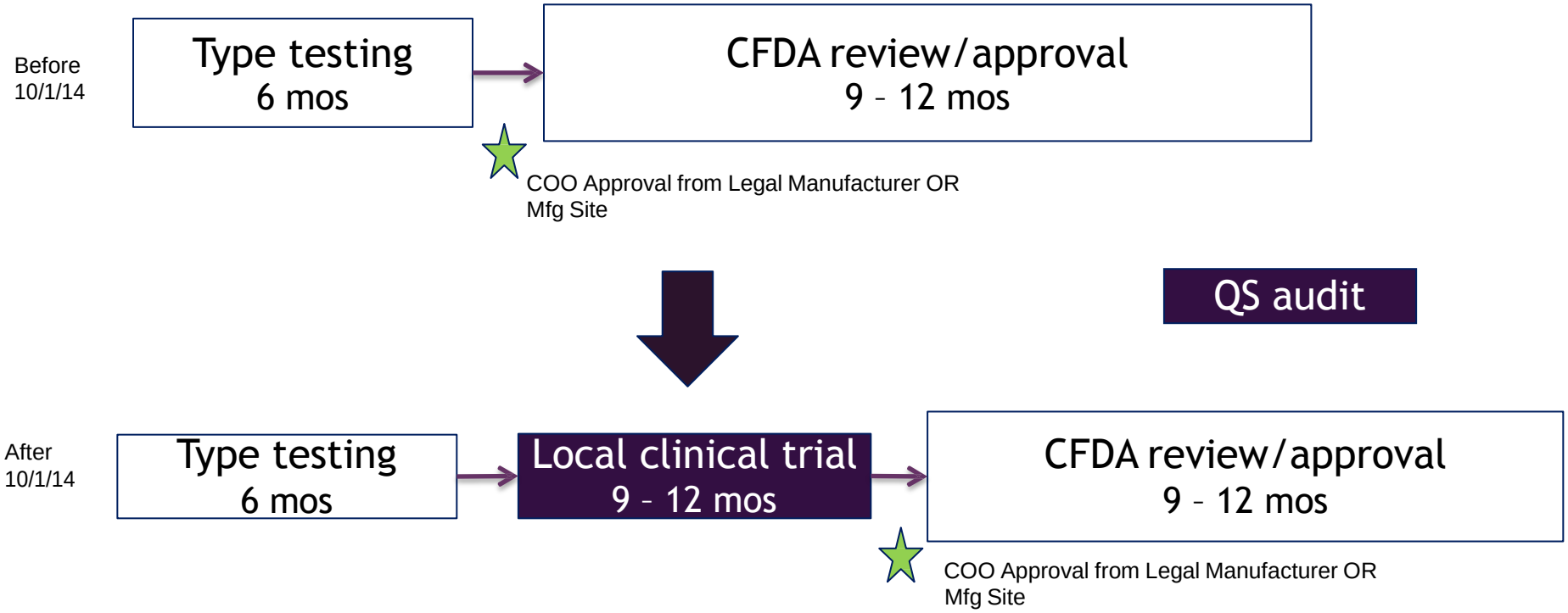
1. In-China clinical trials: required for Class II and III imported medical devices
2. In-China clinical trial can only be conducted after successful completion of type testing
3. On-site Quality System audit: moved to during product registration, risk based, and manufacturers outside of China may be audited
4. More technical documents are required
5. Potential overseas Auditing
6. Longer evaluation time for class III Devices:
   - 90 working days for class III devices. Change evaluation time from 60WD to 90WD assuming no supplement requirement
   - 60 working days for class II devices. No change to evaluation time for class II devices assuming No supplement requirement

Key Changes in Registration Requirements

Removing barriers in registration

1. Filing only. Registration approval for Class I MD and IVD is not required.
2. Registration license is valid for 5 years. Extended from 4 years to 5 years.
3. Registration Certificate is reformed, the initial registration number will be kept with device in life time
4. Extended days for submitting supplementary documentation from 60 to 365 days
5. Country of Origin (COO) Requirement:
   COO from Legal Manufacturer OR Manufacturing Site
6. Exemption from the clinical trials requirements is feasible for products listed in the Catalogue of Clinical criteria for clinical exemptions:

Clinical Trial Impact On Product Registration Timeline (for Imported MD)

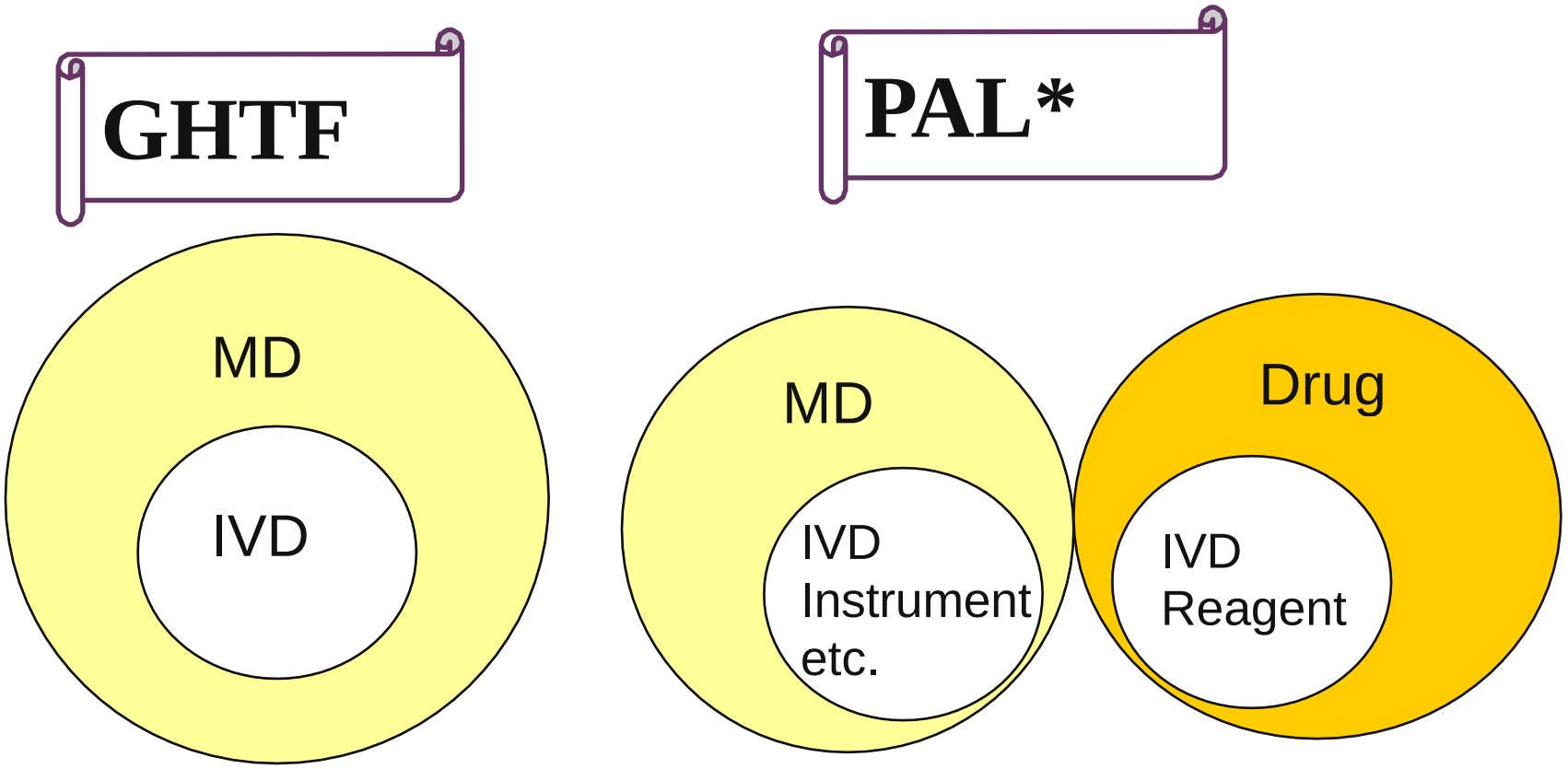


New regulation results in 9 - 12 mos **longer** timeline for registration due to clinical trial requirement

New Regulation Update – India

- Regulation:
  1. India-specific labels are required for both regulated and un-regulated products imported to India by September 27, 2014
  2. Specifically the following information is mandatory: manufacturing date & expiry date, MRP or "Not intended for retail sale", import license #, customer care phone number in India, registered address in India, warehouse address in India, legal manufacturer name and address, and manufacturing site
- Key Challenges:
  1. Products must be India label compliant BEFORE they are imported. labeling operation cannot be done in India.
  2. Small packages cannot accommodate the additional information.
  3. Short transition period (6 months)
- Advocacy Success:
  1. Additional Labelling can be added to products after imports in India
  2. Small label exemption: India specific labelling can be provided on Shelf Carton only
  3. Products for use by Hospital/Diagnostic labs (not supplied to customers directly) are exempted for India Specific Labelling on unit pack

New Regulation Update –Japan
(IVD in GHTF vs. IVD in PAL)



* Pharmaceuticals Affairs Laws (PAL) is revised to be PMD (Pharmaceuticals and Medical Devices) Act

New Regulation Update –Japan

Major changes

PMD Act = PAL +Medical Device specific requirements

- In new PMD Act, more medical specific requirements are added
- Creation of new MAH license category that is specific to IVD reagent
- Standalone software will be regulated as MD (currently non-PAL)
- Regenerative medical products will be defined and covered by PMD Act
- Expand 3rd party review to higher class MD
- FMA (Foreign Manufacturer Accreditation) is relaxed from "accreditation" to "registration"
- QMS (for manufacturer) and GQP (for MAH) requirements will be merged into one
- MAH in Japan will have more supervisory responsibility for product life cycle management

Effective Implementation Time

Implementation November 25, 2014

New Regulation Update – Malaysia

- Medical Device Regulation has been approved and published in the Gazette on 31st Dec 2012
- The effective date of the Act 737 is on 30th June 2013
- The effective date of the Regulation is on 1st July 2013
- By 2015, mandatory enforcement will take place for medical device registration

Definition of Medical Device

SECTION 2 OF ACT 737

"**Medical device**" means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:
   (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
   (ii) compensation for an injury;
   (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;
   (iv) supporting or sustaining life;
   (v) control of conception;
   (vi) disinfection of medical devices;
   (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

   which DOES NOT achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

Definition of Medical Device

SECTION 2 OF ACT 737

b) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a MEDICAL DEVICE by order published in the *Gazette*

Classification of Medical Device

- The class of medical device is determined based on the Classification Rules *(1st Schedule of MD Regulation)*.

  - 4 classes of medical device
    - Class A: Low risk
    - Class B: Low moderate risk
    - Class C: High moderate risk
    - Class D: High risk

Classification of Medical Device (Cont.)

CLASS	RISK LEVEL	DIVICE EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyzer, Prepared Selective Culture Media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy Self-Testing, Anti-Nuclear Antibody, Urine Test Strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood Glucose Self-Testing, HLA Typing, PSA Screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood Donor Screening, HIV Blood Diagnostic

Grouping of Medical Device

- Medical device shall be grouped based on Rules of Grouping *(Regulation 3(1)(b) of MD Regulation)*.

- 6 groups of medical devices are specified:
  i. Single
  ii. System
  iii. Family
  iv. Set
  v. IVD Test Kit
  vi. IVD Cluster

Overview of Registration Process

This slide is sourced from Malaysia Medical Device Authority's presentation slide, and has been modified to explain CAB

New Regulation Update – Philippines

Current – only 5 IVD's categories are required to be registered (Local Testing is required)

- HIV Testing Kits
- Hepatitis B Testing Kits
- Blood Typing Sera
- Pregnancy Test Kits
- Hepatitis C Testing Kits

Feb. 2015 – total 8 IVD categories must be registered (Local Testing is required)

- HIV, HBV, HCV and syphilis kits for: screening, confirmatory, other marks
- Single or combination drug screening test kits for THC, MET, Cocaine, etc.
- Blood typing sera for anti-A, anti-B, Anti-D, Anti-AB
- Anti-human glubulin reagents
- Potentiators such as enzyme, LISS and albumin
- Column agglutination test for crossmatching and blood typing
- Pregnancy test kits
- Leptospirosis test kits

New Regulation Update - South Korea

IVD Reagent Regulation in Korea

- ✓ **Classification** : risk based classifications (Class 1 to 4, low to high)
- ✓ **Regulation** : All IVD reagents are required to be regulated as medical devices (**Effective on Nov 2011**)
- ✓ IVD reagents class 2 to 4 must comply with **Korea Good Manufacturing Practice(KGMP)** quality system
- ✓ **Implementation** of IVD products (Reagents and Device) as medical device step by step from 2011 to 2014

2014

- All IVD reagents are required to be registered as medical device

2013

- Required marketed Class 1&2 IVD reagents had been registered as Medical Device
- Required newly launched Class 3 IVD reagents had been registered as medical device

2012

- Required marketed Class 3 IVD reagents to be registered as Medical Device
- Required newly launched Class 4 IVD reagents to be registered as medical device

2011

Required marketed Class 4 IVD reagents to be registered as Medical Device

Key Challenges

1. General Lack of transparency
2. Insufficient time is allowed for industry to comment
3. No published responses to comments submitted by industry
4. Lack of explanatory information about reasons for new regulatory proposals and objectives to be achieved
5. Usually very short transition periods:
   - China Order No. 650 was published in March 2014, and became effective Oct 1, 2014.
   - China Order 4 – Medical Device Registration Regulation (Order #4) and IVD Registration Regulation (Order #5) were released on July 30, 2014, and became effective Oct. 1, 2014

Summary

1. Very active regulation changes
2. Usually very limited time to comment and implement
3. More technical in nature vs administrative
4. Regulatory convergence?